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K020979

510(k) Summary of Safety and Effectiveness Information
Sysmex® Automated Coagulation Analyzer CA-7000
March 26, 2002

Dade Behring Inc.
13251 NW 9th Terrace
Miami, FL 33182
Contact Person: Radames Riesgo at 305.480.7558 or by facsimile at 305.552.5288

Trade or Proprietary Name: Sysmex® Automated Coagulation Analyzer CA-7000

Common or Usual Name: Automated Coagulation System

Classification Name: Coagulation Instrument (21 CFR §864.5400)

Registration Number:

Manufacturing Site
Sysmex Corporation
Kobe, Japan 9613959

Importer
Sysmex Corporation of America
One Wildlife Way
Long Grove, IL 60047-9596 1422681

Distributer
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101 2517506

The CA-7000 is substantially equivalent in intend use and technological characteristics to the Sysmex® Automated Coagulation Analyzer CA-6000, Sysmex Corporation, Kobe, Japan, which was cleared by FDA under Document Control Nos. K964139, K992321, K993174 and K001145; or the Behring Coagulation System (BCS™ System), Dade Behring, Marburg, Germany, which was cleared by FDA under Document Control Nos. K970431 and K000973.

As demonstrated by clinical correlation studies, the performance claims of the proposed device are similar to the predicate devices. During those studies, specimens were evaluated from apparently healthy individuals and from patients with different pathological conditions which are expected to affect the results for a particular assay. The following summaries show the results of the comparison studies between the proposed and the predicate devices as well as the results of of the precision studies performed with the CA-7000 analyzer.

Summary of Method Comparison Studies Between CA-6000 or BCS

Test	Predicate Device	Sample Number (n)	Coefficient of Correlation (r)	Regression Equitation
Prothrombin Time (Innovin®, seconds)	CA-6000	155	0.999	Y = 0.97X + 0.38
Prothrombin Time (Innovin®, INR)	CA-6000	155	0.999	Y = 0.95X + 0.04
Prothrombin Time (Thromborel® S, seconds)	BCS	174	0.997	Y = 1.09X – 1.54
Prothrombin Time (Thromborel® S, % PT)	BCS	168	0.984	Y = 0.98X – 3.40
Derived Fibrinogen	CA-6000	104	0.991	Y = 1.02X + 0.12
Activated Partial Thromboplastin Time	CA-6000	151	0.997	Y = 1.03X – 0.01
Fibrinogen (Clauss)	CA-6000	134	0.994	Y = 0.91X + 0.05
Factor VII	BCS	124	0.993	Y = 1.14X – 2.66
Factor VIII	BCS	143	0.977	Y = 1.10X – 4.46
Protein C, coagulometric	BCS	139	0.994	Y = 1.14X – 4.77
Thrombin Time	CA-6000	381	0.981	Y = 0.78X + 2.72
Batroxobin Time	BCS	169	0.987	Y = 1.02X + 0.75
Lupus Anticoagulant LA1 Screening Reagent	CA-6000	136	0.996	Y = 0.92X – 1.25
Lupus Anticoagulant LA2 Confirmation Reagent	CA-6000	136	0.953	Y = 0.66X + 10.59
Lupus Anticoagulant LA1/LA2 Ratio	CA-6000	136	0.987	Y = 1.00X – 0.08
Antithrombin III	BCS	166	0.997	Y = 0.96X – 1.07
Heparin, chromogenic	BCS	115	0.982	Y = 1.02X + 0.01
Plasminogen, chromogenic	BCS	142	0.994	Y = 0.96X + 0.55
α2- Antiplasmin, chromogenic	BCS	144	0.982	Y = 0.95X + 3.18
Protein C, chromogenic	BCS	156	0.996	Y = 0.98X – 0.63
Factor VIII, chromogenic	BCS	136	0.990	Y = 1.10X – 1.52

Summary of Precision Studies
Sysmex® Automated Coagulation Analyzer CA-7000

Assay	Control Level	n	mean	Within Run %CV	Between Run %CV	Total %CV
Prothrombin Time (Dade® Innovin® Reagent, seconds)	Control Plasma N Ci-Trol®Control Level3	40 40	11.9 37.2	0.4 0.5	0.2 2.0	0.4 2.1
Prothrombin Time (Dade® Innovin® Reagent, INR)	Control Plasma N Ci-Trol®Control Level3	40 40	1.1 3.4	0.4 0.5	0.2 2.1	0.4 2.1
Prothrombin Time (Thromborel®S Reagent, seconds)	Control Plasma N Control Plasma P	40 40	12.0 25.1	0.4 0.9	0.5 1.1	0.6 1.4
Prothrombin Time (Thromborel®S Reagent, % of norm)	Control Plasma N Control Plasma P	40 40	91.9 36.1	0.6 1.0	0.6 1.2	0.8 1.5
Derived Fibrinogen (Dade® Innovin® Reagent, g/L)	Control Plasma N Path. plasmapool	40 40	1.9 5.7	5.4 3.2	2.2 1.3	5.5 3.3
Activated Partial Thromboplastin Time (Dade® Actin® FSL Reagent, seconds)	Control Plasma N Ci-Trol®Control Level3	40 40	29.6 70.4	0.7 0.6	0.3 0.4	0.7 0.7
Fibrinogen (Clauss) (Dade® Thrombin Reagent, g/L)	Control Plasma N Control Plasma P	40 40	2.5 0.9	1.4 2.5	0.7 1.2	1.5 2.6
Factor VII (Dade® Innovin® Reagent)	Control Plasma N Control Plasma P	40 40	99.7 31.5	2.4 1.7	3.4 2.4	4.1 2.8
Factor VIII (Dade® Actin® FSL Reagent)	Control Plasma N Control Plasma P	40 40	104.6 33.8	6.5 5.9	5.2 3.9	8.1 6.8
Protein C Coagulometric (Portein C Reagent, % of norm)	Control Plasma N Control Plasma P	40 40	112.5 40.9	3.2 4.3	1.2 2.4	3.2 4.6
Thrombin Time (Test Thrombin Reagent, seconds)	Control Plasma N Path. plasmapool	40 40	16.5 19.7	0.6 3.5	1.1 4.4	1.3 5.5

Summary of Precision Studies (Continued)
Sysmex® Automated Coagulation Analyzer CA-7000

Assay	Control Level	n	Mean	Within Run %CV	Between Run %CV	Total %CV
Batroxobin Time (Batroxobin Reagent, seconds)	Control Plasma N Path. plasmapool	40 40	20.1 58.3	1.1 1.2	0.6 0.7	1.2 1.4
Lupus Anticoagulant (LA1 Screening Reagent) (seconds)	Control Plasma N LA Control High	40 40	36.1 90.6	1.6 1.5	2.7 1.5	3.1 2.1
Lupus Anticoagulant (LA2 Confirmation Reagent) (seconds)	Control Plasma N LA Control High	40 40	34.6 40.4	1.0 1.0	0.4 0.9	1.0 1.3
Lupus Anticoagulant (LA1 / LA2) (ratio)	Control Plasma N LA Control High	40 40	1.04 2.24	1.0 1.2	2.5 0.9	2.7 1.5
Antithrombin III (Berichrom™ Antithrombin III (A) Reagent)	Control Plasma N Control Plasma P	40 40	92.6 31.7	1.6 1.8	0.7 0.7	1.7 1.9
Heparin (Berichrom™ Heparin Reagent)	Ci-Trol®Heparin Control Low Ci-Trol®Heparin Control High	40 40	0.06 0.22	7.3 1.9	6.1 2.1	9.2 2.8
Plasminogen (Berichrom™ Plasminogen Reagent) (% of norm)	Control Plasma N Control Plasma P	40 40	101.4 34.6	1.2 1.3	1.4 2.5	1.8 2.8
α2-Antiplasmin (Berichrom™ α2-Antiplasmin Reagent) (% of norm)	Control Plasma N Control Plasma P	40 40	98.8 35.4	1.5 3.2	0.9 1.8	1.7 3.5
Protein C, (Berichrom™ Protein C Reagent) (% of norm)	Control Plasma N Control Plasma P	40 40	101.9 33.3	1.7 2.7	0.8 2.4	1.8 3.5
Factor VIII Chromogenic (Factor VIII Chromogenic Assay) (% of norm)	Control Plasma N Control Plasma P	40 40	107.5 29.6	1.7 1.4	3.8 2.4	4.2 2.8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 7 2002

Mr. Radames Riesgo
Manager, Regulatory Affairs and Compliance
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101

Re: k020979
Trade/Device Name: Sysmex® Automated Coagulation Analyzer CA-7000
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation Instrument
Regulatory Class: Class II
Product Code: GKP
Dated: June 21, 2002
Received: June 24, 2002

Dear Mr. Riesgo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020979

Device Name: Sysmex® Automated Coagulation Analyzer CA-7000

Indications for Use:

The intended use of the Sysmex® CA-7000 is as a fully automated, computerized blood plasma coagulation analyzer for *in vitro* diagnostic use in clinical laboratories.

The instrument uses citrated human plasma to perform coagulation tests.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020979

Prescription Use ✓ **OR** **Over-The-Counter-Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**